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K010610
Pg 1 of 2

SECTION 10
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific chooses to submit a summary of information respecting safety and effectiveness.

Date:	February 28, 2001
Common/Usual Name:	Biopsy Cap; Locking Device
Trade/Proprietary Name:	Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System
Classification Name & Device Classification:	Based on the regulatory class of the predicate devices and the information contained in FDA's classification database, Boston Scientific Corporation believes that the Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System is best described as a Class II device with the following classification names:
Name:	Endoscope and Accessories
Product Code:	KOG
21 CFR Ref.:	876.1500
Device Panel:	Gastroenterology-Urology (GU)/Gastro-Renal (GRDB)
510(k) Sponsor & Owner/Operator:	Boston Scientific Corp. One Boston Scientific Place Natick, MA 01760-1537
Contact Person:	Lisa Quaglia, Regulatory Affairs Manager

K 106101
pg 2 of 2

Device Description:
The Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System consists of a sterile, single-patient use biopsy cap and a rigid plastic guidewire locking device for use with other Boston Scientific Rapid Exchange catheter devices.

Indications for Use:
The Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System consists of accessories intended for use with Microvasive® Biliary Rapid Exchange™ devices.

The Microvasive® Rapid Exchange™ Locking Device is intended to lock the guidewire in place during ERCP procedures.

The Microvasive® Rapid Exchange™ Biopsy Cap is intended to facilitate the use of Rapid Exchange™ devices during ERCP procedures.

Descriptive and Technological Characteristics of Proposed and Predicate Devices:
Boston Scientific Corporation believes that the Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System is substantially equivalent to other devices in the Microvasive® Rapid Exchange™ device family, including the following:

Microvasive® Extractor Rx (K970052)
Microvasive® Ultratome Rx (K970053)
Microvasive® Tandem Rx (K970054)

This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Boston Scientific has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of the internal Risk Analysis procedure. Design Verification testing has been performed to ensure that the Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System meets design specifications.

Conclusion:
Based on the device indications for use, comparison of descriptive and technological characteristics, and design control certification, the Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System has been shown to meet the minimum requirements that are considered acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2001

Ms. Lisa Quaglia
Regulatory Affairs Manager
Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K010610
Microvasive® Rapid Exchange™ Locking Device
and Biopsy Cap System
Dated: February 28, 2001
Received: March 1, 2001
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG

Dear Ms. Quaglia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K010610

Device Name: Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System

Indications for Use:

The Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System consists of two accessories intended for use with Microvasive® Biliary Rapid Exchange™ devices:

The Microvasive® Rapid Exchange™ Locking Device is intended to lock the guidewire in place during ERCP procedures.

The Microvasive® Rapid Exchange™ Biopsy Cap is intended to facilitate the use of Rapid Exchange™ devices during ERCP procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ________
(Per 21 CFR 801.1091)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010610